

Clinical Edit Criteria Proposal

Drug/Drug Class: Opana® Immediate-Release Tablets Clinical Edit

Date: June 20, 2007

Prepared for:

Prepared by: Missouri Medicaid

☒ **New Criteria**

☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Opana® (oxymorphone tablets).

Why was this Issue Selected: Opana® immediate-release tablets are a branded drug product containing oxymorphone HCl. It is indicated for the treatment moderate to severe acute pain where the use of an opioid is appropriate. OPANA, like OPANA ER, is an opioid agonist and Schedule II controlled substance with an abuse liability similar to morphine and can be abused in a manner similar to other opioid agonists, legal or illicit. Opioids are a class of medications that act on common receptors and are natural derivatives of morphine. They are the most potent medications available for treatment of most types of severe pain.

Program-specific information:	Drug	Cost (WAC)
	• Opana 5mg Tablets	\$1.90/tab
	• Opana 10mg Tablets	\$3.45/tab

Setting & Population: Patients 18 years of age and older

Type of Criteria:	<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
	<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

Data Sources: ☐ Only administrative
databases

☒ Databases + Prescriber-
supplied

Setting & Population

- Drug for review: Opana® (oxymorphone immediate-release tablets)
- Age range: Patients 18 years of age and older
- Gender: Male and female

Approval Criteria

- Appropriate diagnosis – (may be subject to clinical review)
 - Cancer
 - Chronic Non-Malignant Pain (CNMP)

Approval Procedures				
Condition	Submitted ICD-9 Diagnoses*	Inferred Drugs	Date Range	Client Approval (Initials)
Cancer	140 – 208	Antineoplastics	2 years	
Chronic Non-Malignant Pain (CNMP)	282 - 355 710 - 733.7	NA	1 year	
	NA	Non-opioid analgesics	90 days	

Denial Criteria

- Dosing schedule exceeding 100mg/day
- Lack of appropriate diagnoses
- Claims for patients under 18 years of age (require clinical consultant review)

References

1. Facts and Comparisons, pg. KU-110. 2006.
2. USPDI, Micromedex, 2006.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2006.
4. Endo Pharmaceuticals, "Opana Product Submission", Chadds Ford, PA, 19317; July 2006.

